Serial No.: 10/568,324 Filed: October 13, 2006

Page : 15 of 23

REMARKS

Claims 3-35, 38-44, 46-48, 59 and 62 have been amended. No new matter has been added. Support for the amendments may be found at, for example, the originally filed claims. Claims 52-58 and 64-67 have been cancelled without prejudice. Applicants reserve the right to prosecute the subject-matter of these claims at a later date.

Claims 1-51 and 59-63 are currently pending.

ELECTION/RESTRICTIONS

The Examiner has withdrawn claims 37 and 38 from consideration as the Examiner contends that those claims are drawn to a nonelected group and species. See Office Action at p.

2. Applicants respectfully request that the Examiner reconsider the withdrawal of claims 37 and 38 and rejoin them for prosecution. An election of subject matter of claims 37 and 38 was not previously requested.

The Examiner previously required the election of the <u>bacteriocin species of claim 12</u> and Applicants duly elected *Lactococcus*-derived bacteriocin species. The subject matter of claims 37 and 38 were not subject to this election because the scope of these claims is not affected by election of a bacteriocin species. Instead, claim 37 is concerned with <u>the micro-organism on which the bacteriocin has an effect</u>. Thus, the species in claim 37 is not a bacteriocin and should not have been considered as being limited for examination by the election of species in claim 12. Claim 38 is dependent on claim 37 and for the reasons stated above, should be considered for examination as well.

SPECIFICATION

The Examiner has requested that the trademark term "Nisaplin" be capitalized and identified as a trademark within the specification. See Office Action at p. 2. Applicants have amended the specification and Figure 1 in accordance with the Examiner's request.

CLAIM OBJECTIONS

The Examiner has objected to claims 4-23, 25, 26, 28-35, 38-42, 44, 46-48, 62 and 63 for being in improper form. See Office Action at p. 2. Claims 25, 26, 28-35, 38-42, 44, 46-48, 62

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 16 of 23

and 63 have been amended to remove multiple dependencies. Applicants respectfully request the withdrawal of this objection.

CLAIM REJECTIONS

Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 59-62, 66 and 67 under 35 U.S.C. § 101 "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process" See Office Action at p. 3. Claims 66 and 67 have been cancelled thus rendering this rejection moot with respect to those claims.

Claim 59 has been amended to include the language "wherein (a) and (b) are contacted with the material." Accordingly claim 59 and its dependent claims 60-61 sets forth the necessary steps for the claimed use. Claim 62 has also been amended in a similar manner. Applicants thus respectfully request the withdrawal of this rejection with respect to those claims.

Rejection under 35 U.S.C. § 112

The Examiner has rejected claims 1-36, 39-51, 59-62, 64 and 66-67 under 35 U.S.C. § 112, second paragraph as being indefinite. See Office Action at p. 3.

With respect to claims 59-62, 66 and 67, the Examiner contends that "it is unclear what method/process applicant is intending to encompass" and that "[a] claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced." See Office Action at p. 3-4. Claims 66 and 67 have been cancelled thus rendering this rejection moot with respect to those claims. Applicants have amended claims 59 and 62 to recite "wherein (a) and (b) are contacted with the material." As such, claim 59, its dependent claims and claim 62 are clear.

With respect to claims 1-36, 39 and 51, the Examiner contends that "claim 1 recites the broad recitation 'an antimicrobial material,' and the claim also recites 'consists of nicin' which is the narrower statement of the range/limitation" and thus the claims are indefinite. See Office Action at p. 4. Claims 2-36, 39 and 51 depend from independent claim 1. Applicants submit that claim 1 states "wherein when the antimicrobial material consists of nisin, the composition comprises" It is clear that the antimicrobial material can be any antimicrobial material and

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 17 of 23

that when the antimicrobial material consists of nisin, the composition includes a number of other specific components. Such a feature does not result in both a broad range and a narrow range being present in the same claim but rather results in the limitation that requires specific further components when the antimicrobial material is nisin.

With respect to claims 64 and 66-67, Applicants have cancelled those claims in an effort to expedite prosecution.

Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 103

Sonnenberg

The Examiner has rejected claims 1-11, 13-20, 22-36, 47-51, 59, 61-64 and 66-67 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0173436 to Sonnenberg et al. ("Sonnenberg"). See Office Action at p. 5. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 64 and 66-67 have been cancelled thus rendering this rejection moot with respect to those claims. Claims 2-11, 13-20, 22-36, 47-51 and 62-63 depend from independent claim 1. Claim 61 depends from independent claim 59.

Claim 1 relates to a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Claim 59 relates to the use of (a) an antimicrobial material, and b) an extract obtained from or obtainable from a plant of the Labiatae family, for preventing and/or inhibiting the growth of, and/or killing a micro-organism in a material; wherein (a) and (b) are contacted with the material; wherein (a) and (b) are different; wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 18 of 23

than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Specifically, the Examiner has alleged that by teaching rosemary, Sonnenberg intrinsically teaches phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid. See Office Action at p. 5. Further, the Examiner has alleged that the specific concentrations featured in the present claims are also obvious as the optimization of general conditions by the person skilled in the art is considered to be routine. See Office Action at p. 6.

It is respectfully submitted that the Examiner is incorrect in her analysis of Sonnenberg for the following reasons. Firstly, it is noted that Sonnenberg is concerned with a process for making a multiphase soup with different sections or phases, which remains stable and *does* not split apart or break. See paragraphs [0012]-[0014] of Sonnenberg. Although Sonnenberg appears to refer to an antimicrobial composition in that it is concerned with soap, such antimicrobial action is of secondary importance. What is most relevant in Sonnenberg, and which therefore would be considered by the person skilled in the art to be the over-riding teaching, is the ability of the soap to have more than one phase and remain intact over long periods of time. See for example, paragraphs [003]-[0014] of Sonnenberg. Thus, when seeking to produce a composition including an antimicrobial material, the person skilled in the art would not even be motivated to turn to Sonnenberg as this reference is of secondary or even lesser importance.

Secondly, and with regard to antimicrobial compositions, all that is disclosed in Sonnenberg are general teachings regarding soap ingredients. Thus, even though the introduction of various additives into soap is discussed (see for example, paragraph [0052]), there is a large number of different additive "types", which a person skilled in the art could add to soap. Further, the list of different individual additive within each "type" is vast. Therefore, once the type of additive has been chosen, the person skilled in the art would then have to make another choice with regard to the specific additive.

Thus, and in view of the fact mentioned above that the person skilled in the art would have no motivation to turn to Sonnenberg, the particular components of claims 1 and 59 must be selected from an extremely vast number of general additives. The subject mater of claims 1 and 59, when starting from Sonnenberg, would not be obvious to the person skilled in the art.

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 19 of 23

Thirdly, there is no single embodiment disclosed in Sonnenberg which features all of the components of claim 1. Thus, there is no indication of any "general conditions," let alone specific conditions or concentrations. As a result, the person skilled in the art cannot be considered to be able to perform routine optimization when the general conditions and even the original embodiment itself are absent from the prior art document.

As such, Sonnenberg does not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Sonnenberg further does not teach or suggest the use of (a) an antimicrobial material, and b) an extract obtained from or obtainable from a plant of the Labiatae family, for preventing and/or inhibiting the growth of, and/or killing a micro-organism in a material; wherein (a) and (b) are contacted with the material; wherein (a) and (b) are different; wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Accordingly, claims 1-11, 13-20, 22-36, 47-51, 59 and 61, are patentable over the Sonnenberg for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Todd, Bard and King

The Examiner has rejected claims 1-36, 39-51, 59-64 and 66-67 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,084,923 to Todd Jr. ("Todd"), U.S. Patent No. 3,679,434 to Bard et al. ("Bard") and U.S. Patent No. 6,451,365 to King et al. ("King"). See Office Action at p. 6. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 64 and 66-67 have been cancelled thus rendering this rejection moot with

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 20 of 23

respect to those claims. Claims 2-11, 13-20, 22-36, 47-51 and 62-63 depend from independent claim 1. Claim 61 depends from independent claim 59.

In particular, the Examiner has alleged that Todd teaches antimicrobial compositions that include, amongst other additives, rosemary extract. See Office Action at p. 6. The Examiner further alleges that Bard teaches the use of polyphosphates in antimicrobial compositions and that King teaches the use of amongst other additives, nisin in antimicrobial compositions. See Office Action at p. 7. The Examiner further alleges that it "would have been obvious to combine all of the claimed ingredients together because they are taught in the reference to have the same purpose." Id. While "[t]he references also do not specifically teach adding the ingredients in the amounts claimed by applicant," the Examiner contends that specific concentrations featured in the present claims are merely the result of routine optimization by the person skilled in the art. See Office Action at p. 7-8. As a result, the Examiner has alleged that the person skilled in he art would combine the teachings of each of the above to arrive at the subject matter of the present claims. See Office Action at p. 8.

Applicants respectfully submit that the above allegations of the Examiner are incorrect. Todd teaches <u>anti-oxidant compositions</u> which includes activated ascorbic acid as an antioxidant. See Abstract of Todd. Todd does not describe antimicrobial compositions. Thus, despite the allegation by the Examiner that the above compositions are used for the same purpose, Applicants submit that Todd is not concerned in any manner with providing an antimicrobial effect and this would not be considered by the person skilled in the art.

King is concerned with providing antimicrobial compositions that include nisin and hops acid extracts. See Abstract of King. Hops acids are chemically different from rosemary extracts and thus their method of action is also different. Hops acids provide an antimicrobial effect through the ability to diffuse across the cell membrane of a bacterium and disrupt the intracellular pH. The resulting disruption in pH affects the electron transfer and cell respiration of the bacterium. By contrast, rosemary extract is an anti-oxidant which does not have a similar effect. In fact, King does not mention that its compositions should have an anti-oxidant effect and anti-oxidants are not even referred to in King. Thus, it is clear that the compositions of Todd and King are used for entirely different purposes; Todd discloses anti-oxidant compositions, but does not mention anti-microbial compositions, whereas King discloses anti-microbial

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 21 of 23

compositions, but does not mention anti-oxidant compositions. Applicants submit that a person of skill in the art would not look to combine the teachings of Todd and King.

MPEP 2145, paragraph X. A, states that "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in that art at the time the claimed invention was made and **does not include knowledge gleaned only from applicant's disclosure**, such a reconstruction is proper" (emphasis added by Applicants) (citing In *re McLaughlin* 443 F.2d 1392, 1395 (CCPA 1971)). Applicants respectfully submit that "[t]he references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention." See MPEP 2141.

It is assumed that the Examiner has cited Bard for being allegedly relevant to the polyphosphates used *in* the *present* invention as chelating agents. However, for Bard to be relevant, a composition comprising an antimicrobial (nisin) and an extract from the member of the labiatae family (rosemary) must first be present. In view of the comments made above with regard to Todd and King, this is clearly not the case. Even if the person skilled in the art were to make the combination suggested by the Examiner (which Applicants submit that they would not), they would still have to provide the components in the specific concentrations featured in present claims 1 and 59. However, despite the allegations of the Examiner, such specific concentrations cannot simply be regarded as "routine optimization."

In order for the person skilled in the art to perform routine optimization on the amounts of specific components in a composition, the person skilled in the art must first know how much of each component is generally present, i.e. they must know the general conditions of the composition. However, in coming to the above conclusion, the Examiner has alleged that the phenolic diterpenes and triterpenes, ursolic acid and rosmarinic acid are all "intrinsically" present. A person skilled in the art can not be expected to perform routine optimization of the concentrations of specific components when no initial general concentration is disclosed.

Thus, even if the combination alleged by the Examiner were to be made (which Applicants strongly submit that it would not), a person skilled in art would not be able to perform routine optimization of the component concentrations and would therefore not find the concentrations in claims 1 and 59 to be obvious.

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 22 of 23

As such, none of the above-cited references, alone or in combination, teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. None of the above-cited references, alone or in combination, teach or suggest the use of (a) an antimicrobial material, and b) an extract obtained from or obtainable from a plant of the Labiatae family, for preventing and/or inhibiting the growth of, and/or killing a micro-organism in a material; wherein (a) and (b) are contacted with the material; wherein (a) and (b) are different; wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Accordingly, claims 1 and 59 and claims that depend therefrom, are patentable over the combination of Todd, Bard and King for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Serial No.: 10/568,324 Filed: October 13, 2006

Page : 23 of 23

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. Should any fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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